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EVALUATION OF THE EFFECTS OF METALLOTHERAPY USED AS AN ANTALGIC IN A GROUP OF PATIENTS TREATED WITH CONVENTIONAL REHABILITATION THERAPY

AIM OF THE STUDY

The aim of this study was to evaluate the effectiveness of the use of some garments in **TEXENERGY** fabric, manufactured by Gafitex, for the reduction of pain symptomatology and of local phlogosis in a group of patients who were known to suffer from arthralgies, affected by acute post-traumatic and/or inflammatory pathology.

INTRODUCTION AND RECRUITMENT OF THE PATIENTS

Acute and chronic joint pain symptoms are more and more frequent nowadays not only in the elderly, who suffer from the ordinary chronic degenerative pathologies, but also in the young who do sports activities at an amateur level: because of athletic gestures frequently performed incorrectly, these young people may suffer from inflammatory and/or traumatic pathologies that are often not easy to cure.

As a consequence, the need to solve the symptom that "pain" is, quickly and by limiting expenses, has become nowadays an important exigency, especially if you consider the great cost of conventional rehabilitation and antalgic therapies (in terms of time, materials and people necessary to administer these therapies), which often have poor or unsatisfactory therapeutic results.

Moreover, the increase in average age and the need to enjoy well-being felt, today more than ever before, also by patients who are no longer young are fundamental exigencies of everyday life.

All these observations point out the clear necessity of an effective therapeutic alternative that can have valid, long-lasting, quick results and, above all, that

can be used at home, without having to go to specialized health institutions, thus allowing a remarkable saving of time.

Bearing this in mind, and in order to test the effectiveness of a new material that exploits the benefits of metallotherapy for antalgic reasons, a total of <u>65</u> <u>patients</u> were selected and recruited for the study. The patients were divided into two groups: the first, including <u>20</u> <u>control patients</u>, well-known to our centre, who underwent ordinary rehabilitation therapies, the second group of <u>45</u> <u>patients</u>, 33 women and 12 men, aged between 23 and 81 (average age 52 and median age 48,4), suffering from several joint, inflammatory, chronic degenerative and traumatic conditions, affecting different parts of the axial and appendicular skeleton.

MATERIALS AND METHODS

The study was carried out on a selected sample of patients, for a total of 65 people, patients of a physic and rehabilitative therapy center, chosen after an accurate clinical check. These people were given garments in **TEXENERGY** fabric, by Gafitex, in their different models, according to the kind of pathology, to be used at skin contact, every day, for at least 8 hours on end and for a period of time not shorter than 2 weeks.

<u>FIRST GROUP</u> (20 control subjects): people who had already undergone a cycle of traditional antalgic therapy, according to well-known protocols fixed by an appropriate specialist prescription (everyday treatment sessions amounting to a complete treatment cycle -2/3 weeks according to the affected joint and to the basic pathology). These people underwent a specialist clinical check before and after the treatment cycle.

This group, not considered in the analysis of the results, was only a reference as to effectiveness and immediacy of the effects of the administered treatment.

<u>SECOND GROUP</u> (45 subjects): invited to associate the conventional therapy with the use of a garment in **TEXENERGY** fabric considered to be the most appropriate to the patient type. This association had to be done immediately after the conventional therapy.

After a clinical evaluation and after explaining every patient the aim and the expectations of the experiment, we gave the participants N. 1-2 garments, relying on a constant co-operation of the patients themselves, who had been informed properly.

The pathology classes included in the analysis of the second group of patients were divided as follows:

chronic degenerative pathologies: 19 patients, 42,2 % traumatic pathologies: 8 patients, 17,8 % inflammatory pathologies: 18 patients, 40 %

The choice of the different joints was made on the basis of each patient's requests and of the high frequency of the pains affecting the joints (table I):

SHOULDER	13
RACHIS	10
KNEE	10
ANKLE	5
ELBOW	4
HANDS AND WRISTS	2
FOOT	1

Upon consent of the patients, an evaluation form was prepared with the following outline:

PART I

Introduction, including the patient's identification data (sex, age, clinical history), the date of recruitment for the study, the location and type of pathology, the consent to the experiment.

PART II

Including subjective evaluation criteria mainly concerning the impressions reported by the patient, with information collected every time.

PART III

Conclusion, including a final evaluation carried out on the basis of both what the patient reported as to an improvement of pain symptomatology and indirectly, as a consequence, of life quality, and of the objective finding by the doctor of clinical signs such as edema reduction, improvement or recovery of joint mobility, signs clearly pointing to an improvement of the patient's general conditions (regular night sleep, normal social life and everyday activities).

EVALUATION FORM - EXAMPLE

Patient's name and address, age, sex, basic pathology, clinical and instrumental exams carried out before the treatment, if any.

Consent.

Patient's evaluation

After using a garment in **TEXENERGY** fabric:

- 1 no improvement 0
- 2 moderate improvement +
- 3 noticeable improvement ++

personal comments

the patient tolerated the use of the garment without any nuisance

the patient noticed the appearance of alterations or redness of the skin

the patient noticed immediate relief, after some days, or only at the end of the treatment cycle

the patient considers this therapy as a valid alternative to traditional antalgic therapies or even better than them

the patient would recommend it to acquaintances and friends

<u>final medical evaluation</u> at the end of the fixed treatment period clinical check, information collection.

RESULTS OF THE STUDY CARRIED OUT ON THE CONTROL GROUP CONSISTING OF 20 PATIENTS

The evaluation of the results coming from the use of the **TEXENERGY** devices by Gafitex was preceded by a therapeutical efficacy analysis of conventional treatments. This analysis was carried out on a control group consisting of 20 patients randomly chosen among those who usually come to our rehabilitation centre, every one or two years, in order to receive conventional antalgic therapies for their different body regions.

As you can see from what follows, it is remarkable that the reduction of pain symptomatology and the subsequent recovery of a moderate condition of well-being was not very satisfactory in most cases (55% of the 20 patients), so much so that the repetition of another treatment cycle or the continuation of the same was foreseen most of the times.

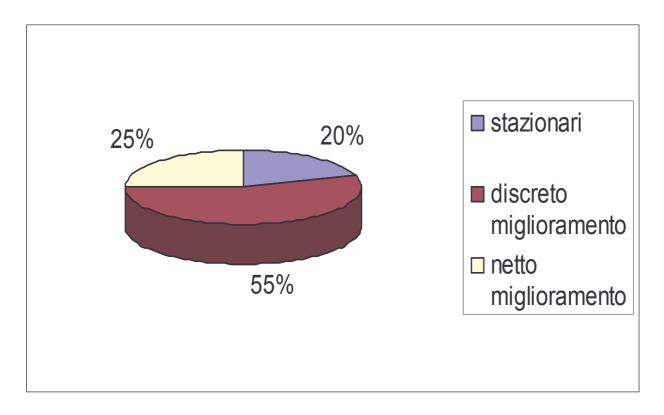
Scheme of the results got in 20 control patients on the basis of the evaluation scale used also for the other 45 patients:

NO IMPROVEMENT	4 patients	(20 %)
MODERATE IMPROVEMENT	11 patients	(55 %)
NOTICEABLE IMPROVEMENT	5 patients	(25 %)

As can be seen from the above-mentioned percentages, only 25% of the patients reported a clear improvement of pain symptomatology and a good recovery of joint mobility, data confirmed by the clinical evaluation as well.

Different pathology frequency in the control group

	20 PATIENTS
6	SHOULDERS
5	SPINAL COLUMNS
6	KNEES
2	HANDS
1	ELBOW

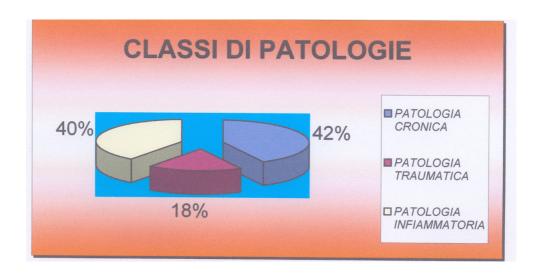


Captions: stazionari = stationary patients discreto miglioramento = moderate improvement netto miglioramento = noticeable improvement

CHART I

Chart showing the therapeutic results of conventional treatment got by the 20 patients of the control group

DETAILS about the 45 subjects who used the devices in TEXENERGY fabric



Captions:

classi di patologie = pathology classes patologia cronica = chronic pathology patologia traumatica = traumatic pathology patologia infiammatoria = inflammatory pathology

Patient N. 1 F.P. aged 68

Affected region: LUMBAR RACHIS

Recurrent lumbago-sciatica

At present undergoing magnetotherapy

Wore PANTIES MODEL "CICLISTA" size M

Patient N. 2 V.R. aged 50

At present complains of aspecific acute gonalgia, without reported traumas Wore **KNEE SUPPORT** size M

Patient N. 3 B. P. aged 81 Affected joint: BILATERAL TIBIO-TARSAL

Arthrosic pathology subsequent to a traumatic sprain

Wore **ANKLE SUPPORT**, size M, 2 supports worn both during the day and at

night, while sleeping

Patient N. 4 V.B. aged 74

Joint: **LEFT KNEE**

Undergoing radar therapy, tens therapy and electrostimulations

Wore **KNEE SUPPORT**, size M

Patient N. 5 M.L. aged 60

Joint: **RIGHT KNEE**

Operated of internal meniscectomy and chondritis on the right side Undergoing magnetotherapy and quadricipital electrostimulation treatments Wore **KNEE SUPPORT**, size M

Patient N. 6 C.P.G. aged 57

Peroneus tendinitis

Joint: **ANKLE**

Wore **ankle-knee support** getting to the heel

Patient N. 7 M.A. aged 56 Wore PANTIES MODEL "CICLISTA", size M

Patient N. 8 S.L. aged **75**Undergoing iontophoresis, electrostimulations
Bilateral gonarthrosis not responding to the different treatments
Wore **2 KNEE SUPPORTS**

Patient N. 9 G.C. aged 39
Suffering from lumbar pain and left coxalgia
Wore PANTIES MODEL "CICLISTA" WITH WAIST SUPPORT

Patient N. 10 S.P. aged 23
Pes anserinus tendinopathy
Wore KNEE SUPPORT

Patient N. 11 C.C. aged 30 Knee medial collateral ligament (MCL) sprain Wore KNEE SUPPORT

Patient N. 12 R.G. aged 47 Chronic epicondylitis Wore ELBOW SUPPORT

Patient N. 13 M. E. aged 26
Elbow joint trauma
Wore ELBOW SUPPORT

Patient N. 14 C.M.G. aged 45
Right epitrochleitis
Wore ELBOW SUPPORT

Patient N. 15 G.A. aged 58 L4-L5 herniated disc with left sciatica Undergoing lumbar kinesitherapy Wore PANTIES WITH WAIST SUPPORT

Patient N. 16 P.C. aged **52** Suffering from recurrent lumbago-sciatica Wore **PANTIES MODEL "CICLISTA"**

Patient N. 17 P.M. aged 58
Suffering from herniated disc
Wore PANTIES MODEL "CICLISTA"

Patient N. 18 C.T. aged 42 Wrist tendinitis

Wore **ELASTIC BANDAGE**

Patient N. 19 D.S.L aged 60

Knee arthrosis

Wore **KNEE SUPPORT**

Patient N. 20 G.L. aged 55

Chronic epicondylitis
Wore **ELBOW SUPPORT**

Patient N. 21 M.T. aged 66

Foot arthrosis

Wore ANKLE SUPPORT

Patient N. 22 M. B. aged 67

Suffering from heel spur Wore **ANKLE SUPPORT**

Patient n. 23 F.M. aged 23

Femoral biceps muscle sprain Undergoing Co2 laser therapy Wore **THIGH SUPPORT**

Patient n. 24 C.A. aged 24

Quadriceps tendinopathy Undergoing Co2 laser therapy Wore **KNEE SUPPORT** (left knee)

Patient n. 25 A.A. aged 66

Acute lumbar pain in arthrosis Undergoing radar therapy

Wore PANTIES MODEL "CICLISTA"

Patient n. 26 A.C. aged 45

Podalgia in hallux valgus Undergoing ultrasound therapy in water and foot iontophoresis Wore **ELASTIC BANDAGE**

Patient n. 27 F.C. aged 66
Scapulohumeral periarthritis, left shoulder
Undergoing tens therapy and ultrasound therapy at the shoulder
Wore SHOULDER SUPPORT NOT ABLE TO WEAR THE GARMENT

Patient n. 28 D.R. aged 44

L5-S1 herniated disc

Undergoing laser therapy, tens therapy, ultrasound therapy and lumbar massotherapy

Wore PANTIES MODEL "CICLISTA"

Patient n. 29 P.C. aged 72
Cervical arthrosis with shoulder pain
Undergoing iontophoresis, tens therapy, ultrasound therapy
Wore SHOULDER SUPPORT

Patient n. 30 E.M. aged 66
Cervical arthrosis with shoulder pain
Undergoing tens therapy and massages
Wore SHOULDER SUPPORT

Patient n. 31 T.G. aged 63
Lumbar arthrosis with lumbago-sciatica
Undergoing tens therapy and magnetotherapy
Wore PANTIES MODEL "CICLISTA"

Patient n. 32 M.T. aged 64
Cervicoarthrosis and left shoulder pain
Undergoing tens therapy and cervical massotherapy
Wore SHOULDER SUPPORT

Patient n. 33 S.L. aged 28
Scapulohumeral periarthritis, left shoulder
Undergoing iontophoresis and ultrasound therapy at the shoulder
Wore SHOULDER SUPPORT

Patient n. 34 F.G. aged **66** Frozen shoulder Undergoing tens therapy and kinesitherapy, right shoulder Wore **SHOULDER SUPPORT**

Patient N. 35 B.M. aged 72
Ankle sprain
Undergoing ultrasound therapy
Wore ANKLE SUPPORT

Patient n. 36 M.M. aged 42 Scapulohumeral periarthritis and shoulder bursitis Wore SHOULDER SUPPORT

Patient n. 37 T.R. aged 36 Lumbar pain Wore PANTIES MODEL "CICLISTA"

Patient n. 38 B.C. aged 62 Shoulder bursitis
Wore SHOULDER SUPPORT

Patient n. 39 B.A. aged 37 Scapulohumeral periarthritis, right shoulder Wore SHOULDER SUPPORT

Patient n. 40 C.R. aged 64
Cervicalgy
Wore SHOULDER SUPPORT

Patient n. 41 P.A. aged 40 Cervicalgy Wore SHOULDER SUPPORT

Patient n. 42 F.A. aged 23
Rotator cuff lesion
Undergoing ultrasound therapy
Wore SHOULDER SUPPORT

Patient n. 43 G.M.V. aged 52 Suffering from rheumatoid arthritis Wore GLOVES

Patient n. 44 B.M. aged 70
Right knee
Doing physical exercise
Wore KNEE SUPPORT

Patient n. 45 F.A. aged 23
Right knee anterior cruciate ligament sprain
Undergoing laser therapy
Wore KNEE SUPPORT

RESULTS AND CONCLUSIONS

The measure of treatment satisfaction was classified on the basis of positive (+ and ++) and negative (-) values.

The use of the device was badly tolerated or not tolerated only by three patients.

The analysis of the results revealed what follows:

72% of the subjects reported a clear improvement caused by the use of the device, even if compared to the ordinary therapies the patients underwent, with complete satisfaction; the clinical evaluation carried out at the end of the required treatment time confirmed a remarkable improvement of the clinical situation (good recovery of joint function and reduction of periarticular edema). 22% of the subjects got good results, better than those got from the conventional treatments they had already undergone.

4% did not get any benefit from the device under examination.

Finally, only 2% could not tolerate the extended use of the device.

The extremely positive results of this study, shown in table II herewith enclosed, are preliminary but, nonetheless, make some remarks possible and let foresee excellent prospects for the future and a wider application field of the devices under examination, if you consider their remarkable therapeutic potentialities.

To be more precise, therapeutic applications in the treatment of localized edemas and of systemic inflammatory arthropathies (e.g. rheumatoid arthritis) seem interesting and promising.

The comparative analysis of the results got in the control group consisting of 20 patients showed clearly that the use of the **TEXENERGY** devices is an important "added value" if compared to the ordinary antalgic treatments.

In particular, the most significant improvements amounted only to 25% in the first group, while they rose to 72% of the total for the 45 subjects included in the second group.

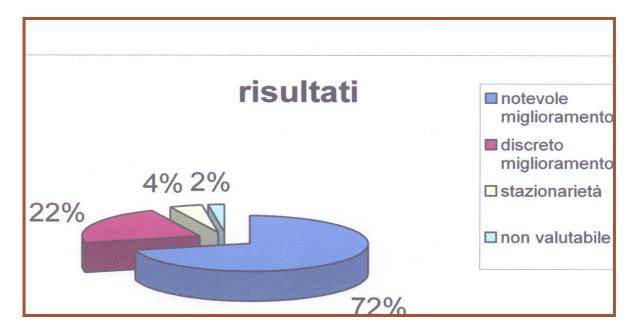
All the recruited patients accepted with favour and with keen interest the proposal to participate in the study. The same interest was also aroused in the technical-sanitary personnel that co-operated in the project.

The patients had an average age of 51, while some older patients did not accept the proposal with favour and they expressed a strong intolerance to having to wear the device for an extended period of time. Moreover, female sex subjects showed to be more co-operative and a stronger liking for the devices to be used for lower limbs and for the distal segments of rachis was observed.

None of the patients ever reported skin alterations, reddening, itches or nuisance.

In conclusion, this stage, preliminary also as to numbers, lets foresee excellent future prospects for the use of the TEXENERGY fabric as an antalgic.

Our centre declares itself willing to carry out other studies on larger groups of subjects, studying them according to kinds of pathology as well.



Captions:
risultati = results
notevole miglioramento = considerable improvement
discreto miglioramento = moderate improvement
stazionarietà = stationary condition
non valutabile = cannot be evaluated

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